the Cochrane Library and PubMed was also conducted using relevant MeSH terms and text words to identify additional reimbursement and HEOR issues associated with regenerative medicines. **RESULTS:** Although considered a nascent field, over 40 HTAs and coverage policies on cellular therapies and regenerative medicines were available from the key Australian, European and North American HTA agencies and payers considered in the assessment. Many of HTAs and coverage policies identified gaps in effectiveness data, particularly the lack of compelling comparative trials and long-term outcomes, and uncertainty surrounding cost-effectiveness. **CONCLUSIONS:** While HTAs and payer policies on regenerative medicines reflected decision factors commonly associated with biopharmaceuticals, other key market access factors beyond clinical- and cost-effectiveness were identified that are specific to this field. These factors include involvement of multiple reimbursable technologies in cell extraction, processing and administration; cell handling steps that may engage multiple healthcare budgets; and requirements to characterize the value of the entire procedure versus the regenerative medicine alone. Key considerations for HEOR and market access planning are considered.

PHP27

DIFFUSION OF INNOVATIONS IN HEALTH CARE: DOES THE DUAL MARKET PHENOMENON EXIST?

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OBJECTIVES: The diffusion of innovative technologies and specifically the difference between early and mainstream adopters during the product's life-cycle (also known as the chasm/saddle phenomena), has been studied empirically. It has been demonstrated that given a dual-market structure (e.g. early vs. mainstream adopters) cost has a substantially higher negative impact on mainstream adoption rate than on early adoption rate. Previous studies focused primarily on the consumer electronics industry. We examined whether the phenomena of dual-markets exists also for medical technologies. **METHODS:** We analyzed the diffusion of innovation patterns of 11 medical interventions using a recent mathematical model: the Change of Dominance (CD) model, which analyzes the dynamics between the early and mainstream adopters. Previous research concluded that influences on adoption and subsequent diffusion rates are very different for various health categories, technologies, and geographies. Therefore, our empirical dataset covered three major medical intervention categories: interventional procedures (e.g. coronary stents), pharmaceuticals (e.g. beta-blockers), and diagnostic technologies (e.g. CT scans). The dataset was collected from five countries: United States, UK, Korea, Canada and New Zealand. **RESULTS:** The CD model has an excellent fit (>90%) to all of the technologies analyzed. Nine of the 11 technologies examined (82%) reached major market adoption. The median time of change of dominance for these nine technologies was seven years, very similar to that found for consumer electronics. The adoption rate at the time of CD is ~25%, which is higher than the rate in consumer electronics markets. The CD time of interventional technologies (e.g. coronary stents, bypass surgery) was substantially lower (3 vs. 8.5 years) compared to pharmaceuticals or diagnostic technologies. **CONCLUSIONS:** The dual market phenomenon seems to occur in the health care, with similar patterns to the consumer electronics industry. Both technology manufacturers and health planners should consider these findings when attempting to promote the use of innovative technologies.

PHP28

DRUGS FOR RARE DISEASES: INFLUENCE OF OPRHAN DESIGNATION STATUS ON PRICE

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OBJECTIVES: The literature indicates that the expenditure on orphan drugs will be increasing over the coming years. The market for orphan drugs has inherent market characteristics that sometimes result in high prices. The aim of this study was to analyse whether awarding orphan designation status has an influence on the price setting of drugs for rare disease indications. **METHODS:** To this effect, prices of designated orphan drugs were compared with other non-designated drugs for rare disease indications. We identified 28 designated orphan drugs and 16 comparable non-designated drugs for rare disease indications for which we collected official hospital prices (per defined daily dose) in Belgium in 2010. **RESULTS:** Orphan-designated drugs had a higher median price (€138.56 [interquartile range; IQR €406.57]) than non-designated drugs (€16.55 [IQR €28.05]) for rare disease indications ($p < 0.01$). **CONCLUSIONS:** In conclusion, our results suggest that awarding orphan designation status in itself is associated with higher prices for drugs for rare disease indications. In order to gain full insight into orphan drug pricing mechanisms, future research should focus on collecting information about the different factors influencing orphan drug pricing.

PHP29

IMPACT OF DIFFERENT PHARMACEUTICAL DISTRIBUTION SYSTEMS ON THE ACCESS TO PHARMACEUTICAL PRODUCTS IN SIX EUROPEAN COUNTRIES

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OBJECTIVES: The pharmaceutical-sector is vital for the society and economy as a whole. Wholesalers are essential for the distribution-chain because they bridge time and space between supply and demand. Thus, the study aims to draw a comprehensive picture of the Pharmaceutical-Wholesale-Industry, outlining its socio-economic importance compared to other forms of distribution with qualitative and quantitative methods, focusing on Germany, U.K., France, Italy, Spain and the The Netherlands. **METHODS:** The necessary data was obtained from different sources: an online-questionnaire was directed to pharmacies, annual GIRP and IMS-Health statistics; a questionnaire was directed to GIRP-full-member associations and Wholesale companies (return rate 81%); and systematical literature research which verified the empirical findings. **RESULTS:** If pooling of medicines would not be ensured by Wholesalers, each pharmacy would have to contact each Manufacturer in order to obtain a complete assortment of medicines. The continuous supply of medicines involves more than 4.5bn transactions between Pharmacies, Wholesalers and Manufacturers each year. Without Wholesalers this number would dramatically increase to 99.4bn transactions per year. On average Wholesalers are bundling products of 21.84 Manufacturers per delivery. The process-costs of a several order from Wholesalers are €7.98; from Manufacturer €11.36 (cost differences of 21.84 supplies from direct sales: €240.11). These additional costs have to be paid by Manufacturers, Pharmacies and finally by Patients. Furthermore, Wholesalers pre-finance (Ø €11.5bn for 46d) the entire medicine-market and secure the cash-flow of the social-insurers. Regarding satisfaction with different distribution-models, the results of the online-questionnaire show that pharmacists are not satisfied with the new models (satisfaction Wholesalers: 85.17%; Manufacturer: 39.75%; RWA: 9.50%; DTP: 12.2%). **CONCLUSIONS:** A reduction in number of Wholesalers will result in a slower supply of medicines, so the existence of the current distribution system is vital to the European health care sectors, as Pharmaceutical Wholesalers help reducing transaction-cost, secure a safe, rapid and continuous supply of medicines.

PHP30

BIOSIMILARS IN THE EUROPEAN MARKET

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OBJECTIVES: To describe the evolution of biosimilars in the EU Member States (MS) and to identify the key parameters of the EU biosimilars market dynamics across countries: time to market entry, prices and market penetration. **METHODS:** A quantitative analysis of the EU biosimilar market from 2007 to 2010 was conducted for 26 EU MS. Data was obtained from European Medicines Agency (EMA) and IMS MIDAS database, including at country level: Date of market entry of reference products and biosimilars, unit sales and prices (estimated using official prices) of existing biosimilars and their respective reference products. Descriptive statistics were applied to summarize the results. Multivariate regression analysis was applied to identify statistical associations between: 1) time period between the EMA's approval and market entry; 2) market penetration (in monetary value); 3) biosimilars DDD prices and the following independent variables: Pharmaceutical market value, population, Gross National Income, Price Level Index of medicines, total expenditure on health as % GNI, total expenditure on health in absolute terms, government expenditure on health and Generic Price Control, International Price Comparison, Tendering-like practices, Pharmacists generic substitution, INN prescribing, Procedure for pricing and/or reimbursement decision, and Reference Price System. **RESULTS:** The market penetration of biosimilars for the three reference molecules (somatropin, epoietin and filgrastim) rose from 0.33% in 2007 to 15,52% in 2010. The multivariate analysis show an association between the price level index, the total and governmental expenditure on health and an earlier market entry. **CONCLUSIONS:** Biosimilars hold a certain promise to help bring down the cost of biologicals to health systems. Existing evidence in the EU is still limited and the results do not show a clear pattern of market dynamics, although it becomes evident that biosimilars will attain smaller price reductions and market penetration than conventional generics.

PHP31

THE ECONOMIC IMPACT OF SWITCHES OF PRESCRIPTION DRUGS TO THE OVER-THE-COUNTER STATUS (RX-TO-OTC): A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: To review economic evidence supporting Rx-to-OTC switches. **METHODS:** A systematic search of the EMBASE, Pubmed, ISPOR conference abstracts databases and industry associations websites was conducted. The search was limited to years 2000–2010 and to North America and European countries. Two independent reviewers selected eligible studies. **RESULTS:** The search identified 14 reviews, 12 model publications, 12 database analyses, 5 prospective observational studies and 11 other. Most articles originated from the US. In 5/6 database analyses and in 8/9 budget impact models (BIM) that quantified cost consequences of Rx-to-OTC switching, it was shown to generate savings to healthcare budget holders, mainly due to Rx-drug acquisition savings. Other key direct savings included avoided: doctor's visits to obtain a prescription; emergency room visits or hospitalisations due to easier access to an effective or safer therapy. Employers' benefits included less time-off work to obtain a prescription and less absenteeism and presenteeism due to easier access to therapies that improve employee productivity. Cost consequences of potential misuse due to lack of doctor's supervision were frequently acknowledged but rarely quantified. The key factors determining the extent of savings were: uptake rates of the OTC drug among different types of populations (i.e. those on Rx drugs, other Rx drugs, OTC-treated, untreated and undiagnosed), therapeutic area and presence of disreimbursement policies. The only European BIM is old (2004) and showed potential annual savings of €16.4 billion, assuming that 5% of Rx drugs are switched to the OTC status. However, its use is limited as it is not specific to any drug/disease area and took a simplistic